

REMARKS

Claims 21-43 are pending in this Application, with claims 24, 28, 29, and 34-43 having been previously withdrawn. Though no claims have been amended with this Response, Applicant respectfully provides the above claim listing. The Examiner's rejections will now be respectfully addressed in turn.

Rejections under 35 U.S.C. §103(a)

Claims 21-23, 25-27, and 30-33 have been rejected under 35 U.S.C. §103(a) as being obvious NPL to Murray ("Murray" hereinafter) in view of NPL to Allen ("Allen" hereinafter). Applicant respectfully traverses this rejection.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art and that the prior art relied upon, coupled with knowledge generally available in the art **at the time of the invention**, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

Moreover, MPEP 2141.03 that,

"The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art **at the time of the invention**," *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995),

and 103(a) itself states that,

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole

would have been obvious **at the time the invention was made** to a person having ordinary skill in the art to which said subject matter pertains.”

With reference to the U.S. law cited above, Applicant respectfully traverses the Examiner’s reasoning at page 4 of the Office Action, which states that, “One of ordinary skill in the art **at the time of the two references** cited above [Murray and Allen] (2001) would have been motivated to make a radioimmunoconjugate comprising the C595 antibody and the alpha emitter Bi-213 based on the teachings of Murray et al. and Allen et al. The “ineffective” results of treating bladder cancer with alpha emitting radionuclides bound to C595 antibodies demonstrated by the Applicant were performed after the publication of the references cited above.” According to 103(a), this reasoning is clearly improper.

In fact, the results demonstrated in Applicant’s PCT Application are clearly the most pertinent indicators of knowledge to one of ordinary skill in the art **at the time of the invention**. By virtue of inclusion of these results in Applicant’s disclosure, these results are presented at exactly “the time of invention” discussed in 103(a). Consequently, and contrary to the Examiner’s reasoning in the Office Action, the alleged knowledge of one of ordinary skill in the art at the time of the Allen and Murray (2001) publications is not more pertinent than the knowledge of one of ordinary skill in the art at the time of Applicant’s invention (2003). In fact, Applicant respectfully submits that knowledge **at the time of the cited art** is irrelevant to a 103(a) rejection, which is merely concerned with knowledge “at the time of the invention.”

For at least the above reasons, Applicant respectfully asks the Examiner to either remove the 103 rejection over the improper combination Murray and Allen (see below), or issue a new Office Action that addresses the substance (as opposed to the date) of the evidence set forth by Applicant.

Applicant further and respectfully points out that the Seyed reference discusses a difficulty/impossibility in extrapolating from beta to alpha therapy. Indeed, the Seyed

reference indicates that “The pharmacokinetics of **short lived alpha-particles cannot be extrapolated from that of regularly used I-131 or any other long-lived beta-emitter** where it is dominated by biological clearance of the antibody.” Such discussion provides further evidence that replacing a beta emitter with an alpha emitter (as proposed by the Examiner) is an uncommon (if not impossible) practice in the art, and thus certainly not readily obvious to one of ordinary skill in the art.

Having specifically addressed the Examiner’s comments in the most recent Office Action, for the Examiner’s convenience Applicant will now respectfully reiterate the evidence against the combination of Murray and Allen, which was respectfully submitted in Response to the previous Office Action.

Applicant respectfully notes that if proposed modification would render a prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) and MPEP 2143.01 V.

As is set forth by the Examiner in the Office Action of July 1, 2008, Murray teaches a combining of a radioconjugate of C595 with a beta emitter to treat bladder cancer, but does not teach an antibody conjugated to an alpha emitting radionuclide, as is required by Applicant’s claims. Allen teaches the use of alpha emitters with monoclonal antibodies, and the Examiner alleges that this teaching in Allen, as combined with Murray, remedies the deficiencies of Murray via an alleged combined teaching of an alpha emitting radionuclide bound to C595.

However, Applicant respectfully points out that such a combination of Allen and Murray would render Murray unsatisfactory for its intended purpose of treating **bladder cancer**. This is because, as is evidenced by and stated at page 9 line 21 of Applicant’s PCT Application, alpha emitting radionuclides bound to C595 antibodies have been found to be **ineffective in treating bladder cancer**. Thus, if one were to replace the beta emitters of Murray with the alpha emitters of Allen, as would be necessitated by the Examiners proposed combination/modification of the references, the treatment taught in

Murray **would be ineffective with regards to bladder cancer**. As the stated and intended purpose of Murray is to treat bladder cancer (see the title of Murray), Murray would thus be rendered unsatisfactory for its intended purpose. Therefore, a combination of Murray and Allen is improper because there is no suggestion or motivation to make the proposed modification (*In re Gordon*, MPEP 2143.01 V).

As there is no motivation to combine Murray with Allen, Applicant respectfully submits that *prima facie* obviousness does not exist regarding claims 21-23, 25-27, and 30-33 with respect to the proposed combination of Murray and Allen. Thus, one of ordinary skill in the art would clearly not have a reasonable likelihood of success in forming the claimed invention by modifying or combining, or be able to teach every element of claims 21-23, 25-27, and 30-33 by modifying or combining. Thus, here again, *prima facie* obviousness does not exist. *Id.*

Conclusion

Applicant believes that all of the outstanding objections and rejections have been addressed herein and are now overcome. Entry and consideration hereof and issuance of a Notice of Allowance are respectfully requested.

Applicant hereby petitions for any extension of time under 37 C.F.R. 1.136(a) or 1.136(b) that may be necessary for entry and consideration of the present Reply.

If there are any charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicants' attorneys.

The Office is invited to contact applicant's attorneys at the below-listed telephone number concerning this Amendment or otherwise regarding the present application.

Respectfully submitted,

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